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1. Transmitted is a complete revision to Department of Veterans Affairs, Veterans Health Administration Manual M-2, "Clinical Programs," Part VI, "Pathology and Laboratory Medicine Service," Chapter 7, "Infectious Diseases, Infection Control, and Epidemiology," formerly entitled "Investigating Food Poisoning."

2. Principal changes are:

a. Paragraph 7.01: Establishes policy for infection control in VA medical centers;

b. Paragraph 7.02: Describes the function of the medical centers's infection control committee;

c. Paragraph 7.03: Prescribes regulations for cultures taken from employees and the medical center environment;

d. Paragraph 7.04: Delineates regulations for laboratory procedures associated with employee testing;

e. Paragraph 7.05: Describes regulations for dealing with biosafety for organisms transmitted through aerosols; and

f. Paragraph 7.06: Provides regulations for assessment of food borne illnesses.

3. Filing Instructions

Remove page

29

Insert pages

7-i through 7-ii

7-1 through 7-7

4. RESCISSIONS: M-2, Part VI, Chapter 7, change 65, dated September 14, 1983; and VHA Circular 10-91-029.

Signed by Dennis Smith 1/10/94
for

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Acting Under Secretary for Health

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RESCISSIONS

The following material is rescinded:

1. Manuals

M-2, Part VI, Chapter 7, change 65, dated September 14, 1983.

2. Circulars

10-91-029

CHAPTER 7. INFECTIOUS DISEASES, INFECTION CONTROL, AND EPIDEMIOLOGY

7.01 POLICY

It is Veterans Health Administration (VHA) policy that all main clinical laboratory and ancillary testing programs and activities:

- a. Comply with current VHA directives and other applicable standards related to infection control;
- b. Assist facility management to address potential sources of environmental contamination that could adversely impact beneficiaries, visitors, and employees;
- c. Ensure that cost-effective culturing is implemented throughout the facility; and
- d. Ensure that cultural results can be interpreted suitably and will enable the development of appropriate corrective action(s).

7.02 FACILITY INFECTION CONTROL COMMITTEE

The Infection Control Committee provides oversight for the review of culture results, develops tolerance limits and intervention strategies, and develops corollary investigations when intervention is unsuccessful.

a. Representation. Each main clinical laboratory must have a permanent representative on the facility Infection Control Committee. It is recommended that the laboratory Director, the supervisor of the Microbiology Section, or other laboratory personnel knowledgeable about environmental cultures, pseudoepidemics, and other microbiological phenomena serve on the Infection Control Committee.

b. Executive Council. The Executive Council is a subcommittee of the Infection Control Committee.

(1) This Council consists of:

- (a) The chairperson of the Infection Control Committee,
- (b) The facility infection control officer,
- (c) The laboratory's representative on the Infection Control Committee, and
- (d) Other personnel knowledgeable about epidemiological and microbiological phenomena.

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(2) The Council evaluates the:

(a) Need and rational concerning cultural intervention practices for apparent epidemic (or pseudoepidemic) investigations;

(b) Design and conduct of emergency investigations; and

(c) Applicability of investigative epidemiology, prior to the analysis of cultures.

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c. Reports

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(1) Each laboratory must provide monthly reports to the Infection Control Committee or the facility infection control officer. The content and format of these reports should be coordinated with the Infection Control Committee and should include:

- (a) Reportable results (or organisms) found in routine diagnostic cultures;
- (b) Agents that must be reported to local or State governments;
- (c) Organisms that necessitate special isolation procedures (e.g., multiple antibiotic resistant organisms);
- (d) Summary reports of dialysis water cultures;
- (e) Quarterly monitors for skin contaminants in blood cultures;
- (f) Biological indicator (spore test) results on autoclaves throughout the facility;
- (g) Results of infection control cultures; and
- (h) Other total quality improvement reports, as appropriate.

(2) The results of cumulative susceptibility tests (antibiogram) and an assessment of increasing levels of resistant microorganisms in nursing care units must be provided to the Infection Control Committee annually.

7.03 CULTURES

The Infection Control Committee reviews rationale for routine infection control cultures, culture protocols, and resulting corrective action(s). Except for the cultures listed as follows, routine infection control cultures must be authorized by the Infection Control Committee:

a. Employee Health Cultures

(1) Cultures for Symptomatic Employees. Cultures for symptomatic employees of occupational-related illnesses may be analyzed, if the cultures are required by law or policy to discontinue or to return to work. Only the Employee Health Unit is authorized to collect and request analysis of such cultures. Results must be provided to the Employee Health Unit and the infection control officer.

(2) Cultures for Asymptomatic Employees

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(a) Cultures for asymptomatic employees who are being screened for organisms associated with an epidemic or pseudoepidemic may be analyzed only after epidemiologic investigation by the Infection Control Committee, development of a written plan, and approval by the Executive Council.

(b) The plan must include:

1. The reasons for individual screening,
2. A full epidemiological assessment of the problem to be addressed, and

3. Corrective action(s) to alleviate the problem once the cultural documentation is available.

(3) Other Employee Health Cultures. Other Employee Health Cultures may involve serologic tests for hepatitis, Human Immunodeficiency Virus (HIV), etc., (see par. 7.04). Requirements for employee health follow-up after accidental exposure to blood and body fluids are provided by the VA medical center's Employee Health Unit. The employee may elect to have a test for HIV seropositivity or to have serum banked.

b. Environmental Cultures

(1) Dialysis Water Cultures. Dialysis water cultures shall be analyzed in accordance with the latest version of the Association for the Advancement of Medical Instrumentation (AAMI) standard. Results must be provided to the dialysis unit and to the facility infection control officer. NOTE: See the chapter titled "Laboratory Support for Infection Control: Optimization by Policy and Procedure Handbook" in "Clinical Microbiology Procedures Handbook", ed. H. Isenberg 1992 (American Society for Microbiology) for a description of a sample procedure that conforms to the aforementioned standard.

(2) Potable Water Cultures. Potable water cultures shall be analyzed in accordance with the relevant VA standard, (VHA Supplement MP-3, Pt. I, Ch. 2, Par. 2.16). A negative fecal coliform screen (See Standard Methods for the Examination of Water and Waste Water, 17th edition, 1989, American Public Health Association, Washington, DC) can be used as justification to discontinue further testing and to determine that plumbing problems are not detected by this methodology.

c. Other Environmental Cultures. Other Environmental Cultures must be based on a full investigation of the epidemiological circumstances relating to an epidemic or a pseudoepidemic. Analysis must only proceed upon approval of the Executive Council, based upon reviews of the epidemiological and supporting evidence implicating one or more of the devices or agents.

(1) The Executive Council must develop a written plan that describes the epidemiological results, the culture and intervention plan, and the intentions for specific reaction and/or intervention, as a result of the predicted culture results.

(2) Laboratory personnel must develop a thoroughly designed strategy for culture of the product, with consideration for neutralization of antibacterial substances, etc. NOTE: Appropriate storage and handling procedures must be followed at all times.

NOTE: It is recommended that each facility adopt those applicable portions of the Chapter titled "Laboratory Support for Infection Control: Optimization by

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Policy and Procedure Handbook," in Clinical Microbiology Procedures Handbook,
edited by H. Isenberg, (1992) for the control of infection control cultures.

7.04 LABORATORY PROCEDURES ASSOCIATED WITH EMPLOYEE TESTING

a. Written Procedures.

(1) Each laboratory must have written procedures to assure confidential testing and safe banking of serum to protect the specimen from loss, removal, testing without consent, or intentional contamination.

(2) These procedures must control and contain all specimens (including hepatitis, HIV, etc.). These procedures must be approved by the Chief, Pathology and Laboratory Medicine Service.

NOTE: Consideration must be given for the possible social and legal uses for which the results may ultimately be used, and guidance shall be provided on the appropriate tests to be conducted for protocols involving pre-vaccination or post-vaccination or post-exposure testing.

b. Security of Specimens

(1) Each specimen must be appropriately identified and documented so that the identity of these specimens are accurately maintained. If deemed necessary, the specimens shall be identified by numerical codes and appropriately secured.

(2) No specimen may be tested without a signed consent form from the patient and/or employee.

(3) The laboratory responsible for storage of the specimen may not release the specimen without review of the consent form.

(4) A copy of the consent form shall be filed in a permanent location in the VA medical center laboratory.

c. Serum Storage Requirements. Specimens must be stored in an alarmed freezer that does not defrost. The temperature must be -20°C or less (preferably -70°C).

(1) The freezer shall be locked or located in a locked room. Access to the freezer must be limited.

(2) Specimens shall be stored in non-breakable plastic tubes with lids and allowances must be made for expansion during freezing. When the freezer is being maintained or cleaned, specimen boxes must be stored in a nearby freezer.

(3) A second freezer (that meets the same requirements) must be available for use if the first freezer cannot be used (i.e., breakdown, maintenance, cleaning, etc.). The alternate freezer must have sufficient space to enable the safe storage of all specimens.

(4) Laboratory procedures must ensure that specimens will continue to be appropriately identified and handled throughout the transfer process, should it become necessary, to the alternate freezer. NOTE: Specimens must not be allowed to thaw, unless required by the applicable procedure. Thawed specimens shall not be replaced in the freezer.

(5) In the freezer, the specimens shall be systematically stored in boxes (i.e., rows and columns) so that all specimens can be quickly and accurately located. No other specimens shall be stored in these boxes. Boxes must not be removed from the freezer, except to store or remove specimens.

(6) Specimen locations shall be recorded, prior to disposition. Storage documentation must be maintained so that the exact location of each specimen is denoted and must be filed in the vicinity of (not in) the freezer. Prior to removal of specimens from the freezer, these files must be consulted and revised appropriately.

(7) Removal of specimens must be documented and their disposition or destination must be described.

d. Duplicate Samples. Each serum stored shall be placed into at least two separate tubes to allow for confirmation of the results. Only one tube will be sent for testing at a time.

7.05 LABORATORY PROCEDURES ASSOCIATED WITH AEROSOL TRANSMISSION

a. Biosafety Level 3 organisms, as defined by Centers for Disease Control and Protection (CDC), such as Histoplasma, Coccidioides, Blastomyces, and Mycobacterium tuberculosis, are potentially infectious to laboratory workers and staff, visitors, and patients of the hospital by virtue of aerosol dissemination. Effective engineering controls and personal protective equipment can minimize the potential for infections with these agents.

b. Laboratory employees who are potentially exposed to Mycobacterium tuberculosis must be tested for exposure to this organism every year at low-exposure facilities (one that isolates and identifies cultures of any Biosafety Level 3 organisms from six or fewer patients per year) and every 6 months at high-exposure facilities (one that isolates and identifies cultures of any Biosafety Level 3 organisms from more than six patients per year).

(1) Biosafety Level 3 Laboratories. In laboratories that routinely work with bacterial agents such as Mycobacterium tuberculosis in culture or with cultures that yield Histoplasma capsulatum, Coccidioides immitis or Blastomyces dermatitidis, or other Biosafety Level 3 agents, both the design and operation of the facility must adhere to applicable Biosafety Level 3 facility requirements, including:

- (a) Self-closing, double door access;
- (b) Sealed penetrations and windows; and
- (c) Non-recirculated directional airflow.

(2) Biosafety Level 3 Practices. In low-exposure laboratories a modified safety plan, referred to as "Biosafety Level 3 Practices in a Biosafety Level 2 Laboratory," may be appropriate if procedures are restricted to those unlikely to produce aerosols. This modified safety plan must be approved by the Infection Control Committee, the Facility Occupational Safety and Health Committee, and the facility Director. It must specify the actions required for emergency response, clean-up, and evaluation of inadvertent exposures that must be initiated when there is an accident outside the biosafety cabinet.

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(3) Biosafety Cabinet Certification. Biosafety cabinets shall be certified at least once per year in low-exposure facilities and at least twice per year in high-exposure facilities.

(a) Biosafety cabinets are to be recertified after every move, each repair, and when there is work in the vicinity that involves a change in air flow or air pressures.

(b) The certification of the biosafety cabinet must be performed by an individual who is certified by the National Sanitation Foundation.

(4) Biosafety Cabinet Supplementation Respirators. Manipulations involving microorganisms amplified in fluid culture, present a potential for risk of exposure during an unexpected event that compromises the function of the biosafety cabinet. Procedures such as these will be considered high-risk practices.

(a) The laboratory Chief will consult with the facility industrial hygienist to determine if respiratory protection is required and the type of respirator needed.

(b) Employees using respirators will be included in the facility respirator program.

(c) If certain operations in the biosafety cabinet have minimal potential to generate aerosols (e.g., safe bacteriologic loop incineration and specially outfitted funnels for discard) and the certified cabinet has a reliable source of uninterrupted power, occasional transfer of cultured microorganisms from one solid medium to another will be considered a low risk practice.

(d) Extreme care must be taken when specimen processing for mycobacterial cultures requires vortexing the specimen, which is a high risk procedure for creation of aerosols. Increasing the requirements for personal protection during such procedures is necessary to avoid the risk of an unexpected event that compromises the function of the biosafety cabinet. The highest standards of personnel protection must be maintained where possible.

7.06 FOOD BORNE ILLNESSES

a. Initial Assessment. An epidemiologist must evaluate the symptoms, their time of onset, and the relationship to consumption by the involved individual(s) for all suspected food poisoning incidents.

(1) If small numbers of individuals are involved, consult appropriate tables as in the Manual of Clinical Microbiology, 5th Edition, (published by the American Society for Microbiology, Washington, DC) relating symptoms and onset times. These tables may provide sufficient information to enable health professionals in the hospital to logically identify the source of the outbreak.

(2) If large numbers of individuals are involved, the Infection Control Committee should manage the incident. In addition to the facility Director and the Chief of Staff, appropriate local or State public health officials should be notified.

NOTE: No cultures should be analyzed until the initial assessment is completed.

b. Culture Analysis. Based on the initial assessment, afflicted individuals should have appropriate cultures or other tests performed to identify etiologic agents. Cultures for food stuffs, eating and food preparation utensils, or other medical center staff should only be completed upon the approval of the epidemiologist or the Infection Control Committee. Any suspected food stuffs or utensils should be refrigerated, until appropriate studies can be designed to identify the suspected agents or their toxins.

c. Carrier Studies

(1) Based on the results of cultures of afflicted individuals and other tests, the Infection Control Committee may need to design follow-up studies to address the potential role of carriers in introducing the organisms into food stuffs. NOTE: A food microbiologist must be involved in the design of these studies.

(2) Personal hygiene practices at the facility must be modified to address any sources of contamination identified by these studies.

d. Laboratory Resources. If a medical center laboratory does not have sufficient resources for complete and definitive examination of suspected materials, consultation and assistance should be requested from a:

(1) Local, State, or Federal public health service laboratory;

(2) Food and Drug Administration (FDA) laboratory; or

(3) Commercial laboratory that is certified for the evaluation of microbiological safety of foods, as defined in the "Compendium of Methods for the Microbiological Examination of Foods," published by the American Public Health Association.